Aventis CropScience

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454675-00

EPA Correspondence No. 01-06A
June 15, 2001

Ms. Elizabeth Knee
Reregistration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

Re: Brief Comments on the Report from the January HIARC Meeting on Aldicarb

Dear Ms. Knee:

Enclosed, for your information and background, are some brief comments on the February 8, 2001 report from the January 23, 2001 HIARC meeting on aldicarb *(Summary of Toxicology Decisions Impacting Aldicarb Reregistration)*. We believe our previous submissions regarding the three issues identified in the HIARC report were not thoroughly considered by the committee and we strongly object to the conclusions in that report. This summary, together with the aldicarb documents that I sent to you on June 8 *(Significant Correspondence Submitted to Address Aldicarb Issues)*, should provide you with a good background on what Aventis CropScience has already submitted to EPA to address these three aldicarb issues.

Also for your information, I am sending reprints of seven poster presentations presented at the March 2001 meeting of the Society of Toxicologists. Let me know if you need additional copies of any reprint:

1. *Cholinesterase Activity in CD® Rats Following Topical Application of TEMIK® 15G for One Week*

2. *The Toxicokinetics of Peripheral Cholinesterase Inhibition from Orally Administered Aldicarb in Adult Male CD® Rats*

3. *Assessment of Operator Exposure and Risk to TEMIK® 15G (Aldicarb) Incorporating Toxicokinetic Data and Probability Analysis*

4. *Using a Nonlinear Mixed-Effects Model to Characterize Cholinesterase Activity in Rats Exposed to Aldicarb*

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5. *Nonlinear Mixed-Effects Models for Acetylcholinesterase Activity in Humans Exposed to Aldicarb*

6. *Acute Dietary Risk Assessment of Aldicarb, a Carbamate Insecticide Causing Rapidly Reversible Cholinesterase Inhibition*

7. *A Safety Study of Aldicarb at Various Dose Levels in Healthy Male and Female Human Volunteers*

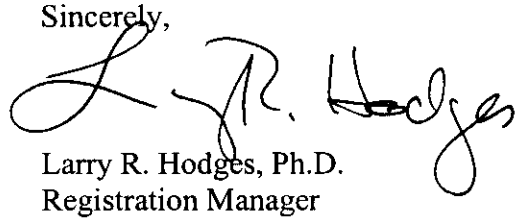
In addition to above summary and reprints that have been provided for your information, Aventis is officially submitting three copies of a document from the Research Triangle Institute study director that factually rebuts EPA's reviews of both TEMIK dermal studies conducted by RTI:

MRID Number 45467501

Tyl, R.W. 2000. Responses to: Health Effects Division Evaluation Records (DER No. 013268: Aldicarb, TEMIK 15G® Grit 21-Day Dermal Toxicity Study and DER 014169: Aldicarb, TEMIK 15G Grit 5-Day Dermal Toxicity Study). Research Triangle Institute, Research Triangle Park, NC. Document No. 01GSP2001. November 15, 2000. 19 Pages.

Please phone me at (919) 549-2870 if you have any questions regarding this submission.

Sincerely,



Larry R. Hodges, Ph.D.
Registration Manager